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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,896	12/21/2001	Viktor Roschke	PA004P1	5432

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EXAMINER	
KENEDY, ANDREW A	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 05/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/023,896	ROSCHKE, VIKTOR	
	Examiner	Art Unit	
	Andrew A. Kenedy	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12 and 25-36* is/are pending in the application.

4a) Of the above claim(s) *12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *12 and 25-36* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicants' cancellation of Claims 1-11 and 13-24, and addition of new Claims 25-36 in the reply of November 3, 2003, is acknowledged. Therefore, Claims 12 and 25-36 are currently pending.

Election/Restrictions

Applicant's election with traverse of Group I (new Claims 25-36) in the reply of November 3, 2003, is acknowledged. The traversal is on the ground(s) that it is not a serious burden to search for both nucleic acid molecules and proteins since Applicants assert that such searches commonly overlap. This is not found persuasive because nucleic acids and proteins are different and distinct chemical compounds as explained in the Office Action mailed October 3, 2003, and would require non-coextensive non-patent literature searches, thereby creating an undue burden of search and examination if they were to be examined together. The requirement is still deemed proper and is therefore made FINAL.

Group II (Claim 12) is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply of November 3, 2003.

Claims

Applicant is advised that should Claim 25 be found allowable, Claims 26 and 27 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing,

despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

According to Table 1A on page 88 of Applicants' specification, amino acid residues 1 to 142 of SEQ ID No. 63 of Claim 25(a) and the amino acid sequence of the complete polypeptide encoded by the HLMIG83 cDNA contained in ATCC Deposit No. PTA-725 of Claim 25(b) are identical. Consequently, sub (a) and (b) of Claim 25 are identically limited polynucleotides. Therefore, Claims 26 and 27 are duplicate claims that are identical to each other and to Claim 25.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 25-36 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial, and credible asserted utility or a well established utility.

On page 49, lines 6-8 of the specification, Applicants assert that the claimed polynucleotide cDNA sequence encodes a gene that "is believed to reside on chromosome 19, specifically at interval D195425-17195418. Accordingly, polynucleotides related to this invention would be useful as a marker in linkage analysis for chromosome 19". This assertion does not constitute a *specific utility* since any other gene residing on chromosome 19 can also be used as a marker in linkage analysis for chromosome 19, and any gene residing within the specific interval D195425-17195418 could be used as a linkage marker for that locus. This

assertion does not constitute a *substantial utility*, since it does not appear that the locus is linked to any particular human disease or disorder.

On page 49, lines 9-23 of the specification, Applicants assert that "This gene is expressed primarily in human breast. Polynucleotides and polypeptides of the invention would be useful as reagents for differential identification of the tissue(s) or cell type(s) present in a biological sample and for diagnosis of diseases and conditions which include but are not limited to: disorders of the reproductive system, such as breast cancer. Similarly, polypeptides and antibodies directed to these polypeptides are useful in providing immunological probes for differential identification of the tissue(s) or cell type(s). For a number of disorders of the above tissues or cells, particularly of the reproductive system, expression of this gene at significantly higher or lower levels may be routinely detected in certain tissues or cell types (e.g., breast, reproductive, cancerous and wounded tissues) or bodily fluids (e.g., breast milk, lymph, serum, plasma, vaginal pool, urine, synovial fluid and spinal fluid) or another tissue or sample taken from an individual having such a disorder, relative to the standard gene expression level, i.e., the expression level in healthy tissue or bodily fluid from an individual not having the disorder." The fact that Applicants indicate that the gene expression product occurs in tissues, cell types and body fluids besides breast tissue, but do not disclose the identity of the particular tissues, cell types and body fluids, necessitates that additional research be performed to reasonably confirm the identity of those tissues, cell types, and body fluids before polynucleotides and polypeptides of the invention could be used as reagents for identification of biological samples and for diagnosis of diseases and conditions. Likewise, Applicants' assertion that higher or lower levels of the gene expression product may be detected in tissues, cells, or body fluids from individuals

with disorders versus individuals without disorders would require additional research to identify the relevant disorders in addition to the relevant tissues, cells, and body fluids. Basic research such as studying the properties of the claimed product itself does not constitute a *substantial utility*. Situations that require carrying out further research to identify or reasonably confirm a "real world" context of use also do not constitute a *substantial utility* (see MPEP § 2107.01, page 2100-32, col. 2).

On page 49, lines 27-30 of the specification, Applicants assert that "the tissue distribution in breast tissue indicates that polynucleotides and polypeptides corresponding to this gene would be useful for the treatment, prevention, detection, and/or diagnosis of tumors, especially breast cancer, as well as cancers of other tissues where expression has been indicated." This assertion does not represent a *substantial utility* since Applicants have not provided information or data from either *in vitro* or animal testing to support the assertion that the claimed gene would be useful for treatment, prevention, detection, and/or diagnosis of tumors. Adequate proof of any such activity or usefulness is simply lacking. Additional basic research would be required to evaluate whether polynucleotides and polypeptides corresponding to the gene would be useful and effective for these applications.

On page 50, lines 5-7 of the specification, Applicants assert that "The breast specific expression and membrane localization indicates that this gene would be a good target for antagonists, particularly small molecules or antibodies, which block functional activity". This assertion is not a *specific utility* since any membrane-localized gene expression product is a better target for antagonists than a product that is localized within the cytosol of a cell where it would be inaccessible to antagonist compounds. Furthermore, while Applicants indicate the

presence of transmembrane domains in the gene product on page 48, lines 21-23 of the specification, Applicants have not provided any evidence to show that the gene product actually localizes to the outer cell membrane rather than to intracellular membranes. Furthermore, it is not clear whether the transmembrane domains are simply putative domains identified by sequence homology comparison or whether they are actually functional. Further still, the assertion lacks *substantial utility* since Applicants have not provided any evidence as to a specific function of the gene product or whether blocking its activity has any useful or clinically-relevant consequence. Here again, additional basic research would be required to evaluate whether the gene product would be useful for the proposed applications.

On page 50, line 23 of the specification, Applicants assert that the gene product has utility as a nutritional supplement. This assertion does not constitute a *specific utility* since any protein can be used as a nutritional supplement (i.e., as a protein supplement at the very least), and Applicants have not provided any evidence to show that the claimed gene product has supplemental nutritional value as anything other than a general protein macronutrient.

On page 50, lines 23-25 of the specification, Applicants assert that "antibodies directed against the protein may show utility as a tumor marker and/or immunotherapy targets for the above listed tissues." The assertion is not a *substantial utility* since Applicants have not provided any evidence to show that the gene or gene product is restricted to, or overexpressed in, any particular tumor type or that it is effective as an immunotherapy target for any tissue. Adequate proof of any such activity or usefulness is simply lacking. Additional basic research would be required to evaluate whether antibodies directed against the protein encoded by the claimed gene would be useful and effective for these applications.

Applicants have not disclosed, and the Examiner is not aware of, any well established utilities for the claimed gene or encoded protein/polypeptide.

Claims 25-36 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial, and credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Made of Record

Prior art of record that is similar to Applicants SEQ ID No. 19 but which was not applied:

GenEmbl Accession No. AC093236.2 (GI:17149385) "Homo sapiens chromosome 19 clone LLNLR-275D8, complete sequence" (29 November 2001) [homology search by USPTO-STIC using GenEmbl database on 20 April 2004]. The antisense of nucleotides 1937-653 of this sequence is nearly identical to sense sequence of nucleotides 1-1285 of Applicant's SEQ ID No. 19. Furthermore, the antisense of Nucleotides 1555-1130 of the sequence is identical to the open reading frame (nucleotides 382-807) of Applicants' SEQ ID No. 19 encoding the polypeptide of Applicants' SEQ ID No. 63, with the exception of a single base pair mismatch at Applicants nucleotide number 725 which results in a single amino acid Valine to Leucine substitution.

GenEmbl Accession No. AC008754.8 (GI:13162498) "Homo sapiens chromosome 19 clone CTD-3023J11, complete sequence" (28 February 2001) [retrieved by USPTO-STIC from

GenEmbl database on 20 April 2004]. The antisense of nucleotides 21775-20491 of this sequence is nearly identical to sense sequence of nucleotides 1-1285 of Applicant's SEQ ID No. 19. Furthermore, the antisense of Nucleotides 21393-20968 is identical to the open reading frame (nucleotides 382-807 of Applicants' SEQ ID No. 19) encoding the polypeptide of Applicants' SEQ ID No. 63, with the exception of a single base pair mismatch with Applicants nucleotide number 725 which results in a single amino acid Valine to Leucine substitution.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew A. Kenedy whose telephone number is (571)-272-0574. The examiner can normally be reached on Monday-Friday 9:00am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571)-272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.A.K. April 29, 2004

Marianne P. Allen 5/3/04

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